Art 34

CLAIMS

1. Use of a test for detecting the genetic basis of Gilbert's Syndrome in a method to improve the efficacy of drug trials, the method comprising screening samples from potential participants for the basis of Gilbert's Syndrome and eliminating or including potential participants in a drug trial in the knowledge of them possessing or not possessing the genetic basis of Gilbert's Syndrome.

2. Use of a test as claimed in claim 1 wherein the method comprise the steps of:

   a) taking a sample from each potential participant in a drug trial,

   b) screening the samples for the genetic basis of Gilbert's Syndrome,

   c) identifying participants having the genetic basis of Gilbert's Syndrome, and

   d) proceeding with drugs trials in the knowledge of participants possessing or not possessing the genetic basis of Gilbert's Syndrome.

3 Use of a test as claimed in claim 1 or 2 wherein the sample is chosen from blood, buccal smear or any other sample containing DNA from the potential participants.

4. Use of a test as claimed in any of the preceding claims further comprising the step of eliminating participants having the genetic basis of Gilbert's

Syndrome from a drugs trial.

5. Use of a test as claimed in any of claims 1 to 3 wherein the method comprises the further step of selecting only participants having genetic basis for Gilbert's Syndrome for a drugs trial.

6. Use of a test as claimed in any of claims 1 to 3 further comprising the step of interpreting the results of the drugs trial in the knowledge that certain participants have Gilbert's Syndrome.

7. Use of a test as claimed in any of the preceding claims wherein the method comprises the steps of:

a) isolating DNA from each sample,

b) amplifying the DNA inner region indicating the genetic basis for Gilbert's Syndrome,

c) isolating amplified DNA fragments, and

d) identifying individuals having the genetic basis of Gilbert's Syndrome.

8. Use of a test as claimed in any of the preceding claims wherein the DNA is amplified using the polymerase chain reaction (PCR) using a radioactively labelled pair of nucleotide primers.

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~~10~~. Use of a test as claimed in any of claims 7 to 9 wherein the DNA region indicating the genetic basis of Gilbert's Syndrome is the gene encoding UDP-glucuronosyltransferase (UGT).

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~~11~~. Use of a test as claimed in any of claims 7 to 10

wherein the DNA to be amplified is in an upstream promoter region of the UGT 1*1 exon 1.

12. Use of a test as claimed in any of claims 7 to 11 wherein the DNA to be amplified includes the regions between -35 and -55 nucleotides at the 5' end of UGT 1*1 exon.

13. A kit for screening individuals participation in drug trials, the kit comprising primers for amplifying DNA in the region of the genome indicating the genetic basis of Gilbert's Syndrome.

14. Primers for use of a test as claimed in any of the preceding claims including primer pairs, AB or CD as follows:

A/B(A,5'-AAGTGAACTCCCTGCTACCTT-3',
B,5'-CCACTGGGATCAACAGTATCT-3') or
C/D (C,5'-GTCACGTGACACAGTCAAAC-3';
D 5'-TTTGCTCCTGCCAGAGGTT-3').